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EXAMINER  
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WASHINGTON, DC 20004

ART UNIT

PAPER NUMBER

20

1805

DATE MAILED: 06/25/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on 3/20/96  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.

**Part II SUMMARY OF ACTION**

1.  Claims 2-14, 16-18, 21-41 are pending in the application.  
Of the above, claims 38-40 are withdrawn from consideration.
2.  Claims \_\_\_\_\_ have been cancelled.
3.  Claims \_\_\_\_\_ are allowed.
4.  Claims 2-14, 16-18, 21-37, 41 are rejected.
5.  Claims \_\_\_\_\_ are objected to.
6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.
7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8.  Formal drawings are required in response to this Office action.
9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).
11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).
12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14.  Other

**EXAMINER'S ACTION**

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1. Newly submitted claims 38-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to a kit. Such claims were non-elected with traverse in Paper No. 8

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-40 are withdrawn from consideration as being directed to a non-elected invention.

See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 3, 6, 7, 8, 9, 10-14, 16, 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al. (U.S. Pat. No. 4,857,318) (A).

Lee discloses a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against *Bordatella pertussis* at 7 and 21 days of age (see column 8, lines 12-13), or at 6 and 12 days of age (column 10, lines 8-15). Although not

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tested in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of diabetes mellitus, since the immunogen is administered in a plurality of doses less than 28 days apart.

4. Claims 2, 3, 6-9, 11-14, 16-17, 21, 22, 25, are rejected under 35 U.S.C. § 102(b) as being anticipated by Barrett et al.

Barrett et al. disclose a method of immunizing a mammal less than 96 months of age against 3 infectious diseases comprising administering to said mammal a vaccine against DPT at four intervals approximately 4 weeks apart starting at 24-48 hours of life (see page 722, first column). Although not tested in the reference, it is considered that the methods disclosed in the reference would inherently produce the claimed effect of reduction of incidence or severity of diabetes mellitus, since the immunogen is administered at least four times during the first 112 days after birth.

5. Claims 21 is rejected under 35 U.S.C. § 102(b) as being anticipated by Halsey et al. (cited by applicants).

Halsey et al. disclose a method of immunization against DPT, wherein DPT immunogens are administered at 7, 35 and 63 days (1, 5 and 9 weeks) of life (see Table 5). Therefore, at least

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two doses were administered at less than 42 days of life. Though not disclosed in the reference, since the method meets the limitations of the claims it is considered that it would result in a reduction of the incidence of diabetes mellitus.

6. Claims 2, 3, 6, 7, 9-14, 16, 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Huang et al. (1984, cited by applicants).

Huang et al. (1984) disclose a method of immunization against pertussis by administering pertussis immunogen at approximately 45, 55, 59 and 85 days of life (see page 221). The incidence of diabetes was reduced.

7. Claims 3, 6-9, 11-14, 16, 17, 25, 28, 29, 30, 31, 33, 34, rejected under 35 U.S.C. § 102(b) as being anticipated by Provenzano et al. (cited by applicants).

Provenzano et al. discloses a method of immunizing against at least two infectious diseases comprising administering immunogens at 0, 3 weeks, 6 weeks, approximately 10 weeks, and 14 weeks of age (see page 959). Although not disclosed, it is considered that this schedule would result in the reduction of the incidence of diabetes.

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8. Claim 24 is rejected under 35 U.S.C. § 102(b) as being anticipated by Provenzano et al. (cited by applicants).

Provenzano et al. teach a method of immunization against at least two infectious diseases, wherein a DPT immunogen is administered in .5 ml. amounts at approximately 10 weeks and 14 weeks of age, and wherein a larger (1ml) dose of pertussis vaccine is administered at 3 and 6 weeks of age (see page 959). Although the incidence of diabetes is not disclosed, it is considered that it would have been decreased.

9. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10. Claims 3, 6-10, 14, 16, are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35

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U.S.C. §103 as obvious over Huang et al. (1991, cited by applicants)

Huang et al. disclose a method of immunization against B. pertussis comprising administering at least 4 doses of an immunogen at four week intervals starting when the mice were 2 weeks old. It is considered that since this protocol meets the limitations of the instant claims, some reduction of the incidence of diabetes mellitus would occur using the disclosed method. In the alternative, if such a reduction did not occur using the disclosed method, it would have been obvious to one of ordinary skill in the art to have varied the timing and/or dosage of immunogen in order to obtain such a reduction, since Huang et al. discloses that this is a desirable result.

11. Claims 4 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee or Barrett in view of Jegede et al. (CD, cited by applicants).

Lee teaches a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against Bordatella pertussis at 7 and 21 days of age (see column 8, lines 12-13), or at 6 and 12 days of age (column 10, lines 8-15). Barrett et al. disclose a method of immunizing a mammal less than 96 months of age against 3 infectious diseases comprising administering to

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said mammal a vaccine against DPT at four intervals approximately 4 weeks apart starting at 24-48 hours of life (see page 722, first column).

The difference between the references and the instant claims is the use of particular immunogen.

However, Jagende teach methods of immunization using such immunogens as an adenovirus immunogen (see page 632).

It would have been obvious to one of ordinary skill in the art to have modified the method of immunization disclosed by Lee et al. or Barrett et al. by including an immunogen such as an adenovirus immunogen, in order to obtain the known benefit of protection against adenovirus infection.

12. Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Lee or Barett et al. (cited above)

Lee teaches a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against Bordatella pertussis at 7 and 21 days of age (see column 8, lines 12-13), or at 6 and 12 days of age (column 10, lines 8-15). Barrett et al. disclose a method of immunizing a mammal less than 96 months of age against 3 infectious diseases comprising administering to said mammal a vaccine against DPT at four intervals

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approximately 4 weeks apart starting at 24-48 hours of life (see page 722, first column).

The difference between the references and the instant claims is the use of parenteral administration of the immunogen.

However, it was well known in the art that different routes of immunization were possible, including intramuscular and parenteral, and could result in varying immune responses. It would have been obvious to one of ordinary skill in the art to have varied the route of immunization as a mere matter of experimental optimization.

13. Claim 18 is rejected under 35 U.S.C. § 103 as being unpatentable over Lee or Barrett in view of Jagende et al.

Lee teaches a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against Bordatella pertussis at 7 and 21 days of age (see column 8, lines 12-13), or at 6 and 12 days of age (column 10, lines 8-15). Barrett et al. disclose a method of immunizing a mammal less than 96 months of age against 3 infectious diseases comprising administering to said mammal a vaccine against DPT at four intervals approximately 4 weeks apart starting at 24-48 hours of life (see page 722, first column).

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The difference between the references and the instant claims is the use of immunogens which are different than those disclosed.

However, Jagende et al. disclose methods of immunizing against rabies, yellow fever, adenovirus, smallpox, cholera, typhoid and plague. It would have been obvious to one of ordinary skill in the art to have substituted a particular known immunogen disclosed by Jagende et al. for those disclosed in Lee or Barrett, in order to obtain immunoprotection against particular infections.

14. Claims 23 and 26 are rejected under 35 U.S.C. § 103 as being unpatentable over Barrett et al. in view of Madore et al.

Barrett et al. disclose a method of immunizing a mammal less than 96 months of age against 3 infectious diseases comprising administering to said mammal a vaccine against DPT at four intervals approximately 4 weeks apart starting at 24-48 hours of life (see page 722, first column).

The difference between Barrett and the instant claim is the inclusion of the administration of a hemophilus influenza immunogen.

However, Madore et al. teach a method for the administration of an hemophilus influenza immunogen at 1 month of life.

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It would have been obvious to one of ordinary skill in the art to have modified the method disclosed by Barrett in order to include immunization against *H. influenza* as disclosed by Madore et al., in order to obtain the benefit of protection against *H. influenza* infection.

15. Claim 27 is rejected under 35 U.S.C. § 103 as being unpatentable over Barrett in view of Madore et al. as applied to claim 26 above, and further in view of Cohen et al. (WO 90/10449) (cited by applicants).

Barett and Madore et al. are cited for the reasons set forth above. The difference between the claims and the references is the further administration of a tolerogen. However, Cohen et al. disclose a method of prevention of diabetes mellitus comprising administering a tolerogen. It would have been obvious to one of ordinary skill in the art to have modified the method of Barett in view of Madore, by including a tolerogen, in order to obtain the desired effect of preventing diabetes, as disclosed by Cohen et al.

16. Claims 30-32 is rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. (A) in view of Schaller et al. (B) (U.S. Pat. No. 4,894,332) or Van Leengoed et al. (U.S. Pat. No. 5,254,340) (C) (newly cited)

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Lee teaches a method of immunizing a mammal less than 96 months of age against at least one infectious disease comprising administering to said mammal a vaccine against Bordatella pertussis at 7 and 21 days of age (see column 8, lines 12-13). The difference between the reference and the instant claim is the additional administration of a vaccine to the mammal of at least 42 days of age.

However, Van Leengoed et al. disclose a method of immunization against an infectious disease, comprising administering a vaccine to a mammal of at least 42 days (see col. 8 lines 60-69), and further administering said vaccine 28 days after the first administration of said vaccine. Schaller et al. disclose a method of immunization against an infectious disease, comprising administering a vaccine to animal of at least 42 days, and further administering said vaccine at 2-4 week intervals for a period of 3 months (see col. 10). It would have been obvious to one of ordinary skill in the art to have modified the method of immunization disclosed by Lee et al., by the additional administration of a vaccine at or after 42 days of age, as taught by Van Leengoed et al. or Schaller et al., in order to obtain the additional benefit of immunoprotection against the virus disclosed by Van Leengoed et al. or Schaller et al. It would have been further obvious to one of ordinary skill in the art to have administered further doses of the vaccine, as

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taught by Van Leengoed et al. or Schaller et al. at approximately 26 or 28 day intervals. It is well known in the art to administer vaccines against two or more diseases, at different ages, in order to provide immunoprotection against infection by said diseases.

17. Claims 28-34, are rejected under 35 U.S.C. § 103 as being obvious over Harris et al. (D) (U.S. Pat. No. 4,152,415) (newly cited).

Harris et al. disclose a method of immunizing a mammal against two infectious diseases comprising administering a vaccine at 7 and 21 days of age, and then given further vaccines daily for 2-6 weeks after 21 days of age (see col. 13, lines 40-55). Though not disclosed in the reference, since the method meets the limitations of the claims it is considered that it would result in a reduction of the incidence of diabetes mellitus.

18. Claim 35 is rejected under 35 U.S.C. § 103 as being unpatentable over Ferreri et al. (R) or (S) (newly cited) in view of General Recommendations on Immunization (AY).

Ferreri et al. (R) or (S) disclose a method for immunization against hepatitis B comprising administering at least one pharmaceutically acceptable dose of hepatitis B vaccine to a

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mammal of at least 42 days of age, and administrating doses at birth and at 15 days of age. The dose at 15 days of age is less than 28 days after the preceding dose. The difference between the claim and the reference is the additional immunization against another infectious disease.

However, General Recommendations on Immunization (GRI) (AY) teaches immunizing infants of at least 42 days of age against multiple infectious diseases using standard vaccines. It would have been obvious to one of ordinary skill in the art to combine the teachings of Ferreri and the GRI, and to immunize young infants against hepatitis B in addition to other infectious disease, in order to obtain the known benefits of protection against infectious diseases.

19. Claim 37 is rejected under 35 U.S.C. § 103 as being unpatentable over Halsey et al. in view of Satoh et al. (cited by applicants).

Halsey et al. disclose a method of immunizing a mammal of less than 96 months of age against at least two infectious diseases comprising administering a vaccine against at least two infectious diseases at 42 days of age (see Table 5). The difference between the reference and the instant claim is the additional administration of an immune modulator at 42 days after birth.

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However, Satoh et al. disclose administering an immune modulator at 42 days after birth (see abstract) in order to prevent diabetes. It would have been obvious to one of ordinary skill in the art to combine the teachings of the two references in order to both protect against infection by certain infectious diseases, and to prevent diabetes, both of which advantages are disclosed in the references.

20. Claim 41 is rejected under 35 U.S.C. § 103 as being unpatentable over Ferreri et al. (R), (S), Lee et al., Barrett et al., Halsey et al., Huang et al. (1991) or Harris et al. (U.S.Pat. No. 4,152,415).

Each of the references teach a method for immunizing a mammal of less than 42 days of age. The difference between the references and the instant claims is the use of a kit for said method.

However, it is well known to utilize a kit (i.e. receptacle containing a product for immunization) for immunization. The content of written instructions and the use of a kit does not render patentability to the method since it constitutes an intended use only and is given little weight.

21. Claim 18 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the

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listed immunogens other than a malaria immunogen or an HIV immunogen. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims recite a method of immunizing against an infectious disease comprising administering particular immunogens, including malaria and HIV. However, applicants have not taught malaria or HIV immunogens which would protect against infection by these organisms. It would require undue experimentation to devise malaria or HIV immunogens which would protect against infection. It is well known that effective vaccines against these diseases have not been produced, and applicants have provided no guidance regarding how to produce such vaccines. The claims should be limited to the immunogens listed other than HIV and malaria immunogens.

22. Claim 33 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is vague and indefinite in its recitation of "each said separate dose is administered during a 0-78 hour period". There is no antecedent basis for the term "separate dose". It is not clear what is meant by a dose being administered over a 0-78 hour period.

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23. Claims 4 and 5 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The claims fail to further limit the subject matter of claim 3, since claim 3 recites that all immunogens are selected from the group consisting of BCG, diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, while claims 4 and 5 recite that one immunogen other than the above listed immunogens (in addition to others) are administered.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-0278. The examiner can normally be reached on Monday through Wednesday from 7:30AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached on (703) 308-0407. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1805 FAX number is (703) 308-0294. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Nancy T. Vogel*  
NANCY T. VOGEL  
PRIMARY EXAMINER  
GROUP 1800

NTV  
June 20, 1996